JUL 2 8 2004

K 041274
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BIOMET

510(k) Summary

Applicant or Sponsor:
Arthrotek. Inc.
(A wholly owned subsidiary of Biomet, Inc.)
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person:
Gary Baker
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (574) 267-6639
FAX: (574) 372-1683

Proprietary Name: Resorbable Interference Screw

Common or Usual Name: Interference Screw

Classification Name: Screw, Fixation, Bone (21 CFR §888.3040)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Arthrotek Interference Screw – Arthrotek Inc. (K982497)
Soft Tissue Screw and Washer – Arthrotek Inc. (K012572)
Resorbable Screw Anchor – Arthrotek Inc. (K012872)

Device Description: The 3 mm, 4 mm, 5 mm, 6 mm, 10 mm, 11 mm, and 12 mm as well as the 9 mm x 35 mm Resorbable Interference Screws are an addition to the 7 mm, 8 mm, and 9 mm interference screws already cleared in 510(K) K982497. They are made of the same LactoSorb® material as the predicate devices.

Intended Use: The Resorbable Interference Screw is intended for soft tissue fixation to bone.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639 ■ FAX
574.267.8157 ■ E-MAIL
biomet@biomet.com

Indications For Use: Indications for the Resorbable Interference Screw includes use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications include the following:

Shoulder: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair.
Wrist/Hand: Scapholunate ligament reconstruction, ulnar/radial collateral ligament reconstruction.
Ankle/Foot: Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.
Elbow: Tennis elbow repair, ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction.
Knee: Extra-capsular repair, medial collateral ligament (MCL) repair, lateral collateral ligament (LCL) repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis reconstruction, patellar ligament/tendon repair, and vastus medialis obliquus (VMO) muscle advancement.

In addition to the above indications, the 7.0, 8.0, 9.0, 10.0, 11.0, and 12.0mm screws are indicated for the following uses:

1. To provide interference fixation of patellar bone-tendon-bone grafts in anterior cruciate ligament (ACL) reconstruction.
2. To provide interference fixation during femoral and/or tibial fixation in anterior cruciate ligament reconstruction using a soft tissue graft (semitendinosus, gracilis).
3. To provide interference fixation during posterior cruciate ligament (PCL) reconstruction.

Summary of Technologies: The Resorbable Interference Screw is made of the same materials, using the same manufacturing processes, and conforming to the same standards as the predicated Arthrotek Interference Screw (K982497). More sizes have been added.

Non-Clinical Testing: Mechanical testing was done on the 3.0 mm Resorbable Interference Screw. This testing indicated that the Resorbable Interference Screw was substantially equivalent to the predicate devices

Clinical Testing: Clinical testing was not required for these components to support substantial equivalence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2004

Arthrotek, Inc.
C/o Mr. Gary Baker
Biomet Manufacturing Corporation
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K041274
Trade/Device Name: Resorbable Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: May 11, 2004
Received: May 12, 2004

Dear Mr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

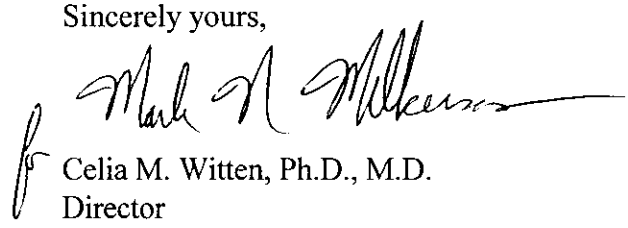
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041274

Indications for Use

510(k) Number: K041274

Device Name: Resorbable Interference Screw

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3. To provide interference fixation during posterior cruciate ligament (PCL) reconstruction.

Prescription Use ✓ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041274